REMARKS

Claims 1-33 remain pending in the application, with claims 29-33 having been allowed, claims 1-15, 19-21 and 23-26 having been rejected, and claims 16-18, 22 and 27-28 having been objected to. Applicants traverse the rejection of claims 1-15, 19-21 and 23-26 for the following reasons. Further examination and reconsideration respectfully are requested.

Explanation of the Amendment

Independent claims 23 and 29 have been amended to clarify in claim 23 that the flexible membrane is constrained so as not to fully open in response to fluid pressure in a forward direction, and to clarify in claim 29 that the flexible membrane is constrained to open no more than about 80 percent of the full open lumen at the edge of the stent corresponding to the inflow edge of the prosthesis upon application of fluid pressure in a forward direction. As explained in the specification at page 8, line 18, through page 10, line 14, the flexible membrane of a stented test structure may be made in any of a great number of different ways to prevent it from opening to a fully open position when appropriate fluid pressure is applied in a forward direction. These ways include, by way of example and not limitation, partially or substantially sealing a flexible membrane, using material or materials for a flexible membrane other than a standard material, thickening a flexible membrane, reinforcing a flexible membrane in different ways, suturing a flexible membrane across a portion of or all of the free edges thereof, and so forth. Hence, the change is fully supported by the specification, and no new matter has been added.

The Examiner Has Misconstrued the Teachings of the Goldstein et al. Reference

While claims 1-15, 19-21 and 23-26 are rejected upon various statutory bases, namely 35 USC §102 and 35 USC §103, the rejections all involve US Patent No. 5,899,937 issued to Goldstein et al. either as the sole reference or as the primary reference in a combination of references. Applicants believe that the examiner's understanding of the disclosure and teachings of Goldstein et al. is not correct, and that

this misunderstanding has resulted in the unwarranted rejection of the claims. Therefore, applicants wish to carefully review the disclosure and teachings of Goldstein et al. on which the examiner relies, before specifically addressing the rejections.

The Goldstein et al. patent is directed to the problem of providing a flow system to assist in transforming a heart valve that is based on a xenograft into an autograft; see column 1, lines 6-8. Goldstein et al. believe that a bioreactor capable of physically preconditioning a living heart valve prior to implantation will be a necessary component of the process of manufacture of these tissue-engineered grafts. According to Goldstein et al., the application of optimal conditions of flow, pulsation rate, and pressure should provide an implant which displays physiologic levels of cellular activity, and provide a graft with extended durability and performance. See column 4, lines 51-58. Therefore, Goldstein et al. has nothing to do with stented test structures.

Although Goldstein et al. used the in vitro flow loop of FIG. 3 to study the cellular activity of a normal, living porcine aortic valve under certain physiologic conditions, they attempted to understand shear stress on the leaflet surface by performing "numerical simulations ... using a finite element solver, the Fluid Dynamics Analysis Package (FIDAP)," column 7, lines 17-19. "Flow through the valves is modeled as flow through an axisymmetric nozzle rather than as a full three-dimensional problem, which greatly reduces the computational time," column 7, lines 28-31. In other words, flow through a physical stented aortic valve with its leaflets fully opened was modeled using the mathematical approximation of flow through an axisymmetric nozzle. A stented aortic valve was modeled rather than a stentless aortic valve only to approximate a worst case situation; see column 7, lines 25-28. Although a stented aortic valve could have been accurately modeled as a full three-dimensional problem, this was not done so that the computational time might be reduced. FIG. 2, therefore, is nothing more than a schematic illustration of certain geometric parameters for the mathematical approximation.

The nozzle shown in FIG. 2 is a mathematical approximation of a stented aortic valve with leaflets fully opened. The nozzle outlet is a mathematical representation of leaflet tips, see column 8, line 15. Goldstein et al. chose a k-6 model from the FIDAP package, with a separate algorithm to capture near-wall behavior, see column 8, lines 1-8. It is clear that the nozzle itself is not a physical thing, and has no physical leaflets.

Correction of the Examiner's Inaccurate Characterization of Applicants' Arguments

In the June 18th Office action, the examiner commented to an extent on applicants' arguments filed on May 24, 2004. One comment is that applicants define "does not fully open" with respect to the inflow edge of the stent. Applicants have not so defined this term.

The examiner also states that "a valve installed in the nozzle when fully open against the walls of the nozzle would only open about 80% of the full open lumen." While applicants traverse the 80% figure, the real problem is that the Goldstein et al. patent does not teach placing valves inside nozzles. As discussed above, the nozzle is a mathematical construct while the valve is a physical thing. Even more compelling is the disclosure by Goldstein et al. themselves as to the design of the aortic test section. The aortic test section has aortic valve samples mounted in parallel; see column 9, lines 54-55. The details of the mounting of the valve samples is disclosed in column 10, lines 6-24, in which nothing is said about mounting valves in nozzles despite the high level of detail given.

The examiner's response to applicants' arguments and continued rejection of claims is based on an erroneous understanding of the disclosure of Goldstein et al. The examiner is respectfully requested to reconsider his position.

All Pending Claims are Patentable over Goldstein et al. Either Alone or in Combination with Pietsch et al. or Eberhardt

Applicants respectfully request the examiner to reconsider applicants' prior arguments of patentability over Goldstein et al. either alone or in combination with Pietsch et al. or Eberhardt. The prior arguments are incorporated herein by reference.

Moreover, amended independent claims 23 and 29 and all claims dependent therefrom are patentable over Goldstein et al. for the additional reason that the flexible membrane is constrained so as not to fully open in response to fluid pressure in a forward direction (claim 23), and that the flexible membrane is constrained to open no more than about 80 percent of the full open lumen at the edge of the stent corresponding to the inflow edge of the prosthesis upon application of fluid pressure in a forward direction (claim 29). As explained above, the Goldstein et al. patent does not disclose, teach or suggest constraining the leaflets in any way. The leaflets in Goldstein et al. are normal leaflets of porcine aortic valves.

In view of the amendments and reasons provided above, it is believed that all pending claims are in condition for allowance. Applicants respectfully request favorable reconsideration and early allowance of all pending claims. If a telephone conference would be helpful in resolving any issues concerning this communication, please contact the undersigned at (952) 253-4135.

Respectfully submitted,
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